

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

|    |   |                 |
|----|---|-----------------|
| 1. | Select appropriate response<br>- Protocol version                           | 30 JUN 2020     |
| 2. | Select appropriate response<br>- What cohort does the<br>subject belong to? | STAGE 3 COHORTS |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Aug/14/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12411117]                                     |
| 2. | Birth Date:                     | (b) (6) 1953                                   |
| 3. | Sex:                            | FEMALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN                      |
| 6. | Racial Designation:             |  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Aug/14/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

|     |                                     |  |
|-----|-------------------------------------|--|
| 1.a | Inclusion Number:                   | 1  |
|     | Criterion Description:              | Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN01A00  |
| 1.b | Inclusion Number:                   | 2  |
|     | Criterion Description:              | Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures                  |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN02A00  |
| 1.c | Inclusion Number:                   | 3  |
|     | Criterion Description:              | Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study                |
|     | Criterion met?                      | YES  |
|     | Criterion ID: (For Pfizer use only) | IN03A00  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                     |   |
|-----|-------------------------------------|---|
| 1.d | Inclusion Number:                   | 4   |
|     | Criterion Description:              | Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol |
|     | Criterion met?                      | YES   |
|     | Criterion ID: (For Pfizer use only) | IN04A00   |

**Exclusion Criteria**

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.a | Exclusion Number:                   | 1   |
|     | Criterion Description:              | Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX01A00   |

|     |                                     |  |
|-----|-------------------------------------|--|
| 2.b | Exclusion Number:                   | 2  |
|     | Criterion Description:              | Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX02A00  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                     |  |
|-----|-------------------------------------|--|
| 2.c | Exclusion Number:                   | 3  |
|     | Criterion Description:              | History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX03A00  |
| 2.d | Exclusion Number:                   | 4  |
|     | Criterion Description:              | Receipt of medications intended to prevent COVID-19  |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX04A00  |
| 2.e | Exclusion Number:                   | 8  |
|     | Criterion Description:              | Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination                      |
|     | Criterion met?                      | NO   |
|     | Criterion ID: (For Pfizer use only) | EX08A00  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.f | Exclusion Number:                   | 10  |
|     | Criterion Description:              | Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX10A00   |
| 2.g | Exclusion Number:                   | 11  |
|     | Criterion Description:              | Women who are pregnant or breastfeeding   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX11A00   |
| 2.h | Exclusion Number:                   | 12  |
|     | Criterion Description:              | Previous vaccination with any coronavirus vaccine   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX12A00   |
| 2.i | Exclusion Number:                   | 13  |
|     | Criterion Description:              | Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids  |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX13A01   |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.j | Exclusion Number:                   | 15  |
|     | Criterion Description:              | Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX14A01   |
| 2.k | Exclusion Number:                   | 16  |
|     | Criterion Description:              | Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation                 |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX15A01   |
| 2.1 | Exclusion Number:                   | 17  |
|     | Criterion Description:              | Previous participation in other studies involving study intervention containing lipid nanoparticles   |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX16A01   |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                     |   |
|-----|-------------------------------------|---|
| 2.m | Exclusion Number:                   | 22  |
|     | Criterion Description:              | Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members |
|     | Criterion met?                      | NO  |
|     | Criterion ID: (For Pfizer use only) | EX21A01   |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/14/2020 |
| 2. | Phase of Disposition:                     | SCREENING   |
| 3. | Status:                                   | COMPLETED   |
| 4. | Specify Status:                           | [ ]         |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                  |
|-----|--|----------------------------------|
| 1.a | Line/MH Number:  | [1]                              |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Systemic arterial hypertension] |
|     | Start Date:  | UNK/UNK/1993                     |
|     | Ongoing:   | YES                              |
| 1.b | Line/MH Number:  | [2]                              |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Osteoarthritis]                 |
|     | Start Date:  | UNK/UNK/2005                     |
|     | Ongoing:   | YES                              |
| 1.c | Line/MH Number:  | [3]                              |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Benign thyroid nodules]         |
|     | Start Date:  | Oct/UNK/2016                     |
|     | Ongoing:   | YES                              |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                                 |
|-----|--|---------------------------------|
| 1.d | Line/MH Number:  | [4]                             |
|     | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [Hysterectomy]                  |
|     | Start Date:  | UNK/UNK/2006                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2006 |
| 1.e | Line/MH Number:  | [5]                             |
|     | Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies: | [allergic rhinitis]             |
|     | Start Date:  | UNK/UNK/2000                    |
|     | Ongoing:   | YES                             |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Aug/14/2020 |
| 2. | Weight:          | [77.1]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [151.5]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [33.6]      |

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 7.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.6]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Aug/14/2020  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |                          |
|-----|-------------|-------------------------------|--------------------------|
| 6.a | Sponsor ID: | [113]                         | <a href="#">Comments</a> |
|     | Test:       | Choriogonadotropin Beta_PX113 |                          |
|     | Result:     |                               | <a href="#">Comments</a> |
|     | Not Done:   | NOT DONE                      | <a href="#">Comments</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Aug/14/2020 |
| 2. | Randomization Number: | [228134]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/14/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP5H0R] |
| 5.b | Sample ID | [BP5H0S] |
| 5.c | Sample ID | [BP5H0T] |
| 5.d | Sample ID | [BLCSS2] |
| 5.e | Sample ID | [BLCSS3] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Aug/14/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BP5H05] |
|-----|-----------|----------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**eCRF Audit Trail History**

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Aug/14/2020 10:46                         |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response<br>- Reactogenicity diary<br>collection | YES - REACTOGENICITY E-DIARY COLLECTED FOR<br>THIS SUBJECT |
|----|---|--|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Sep/4/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |          |
|-----|---|----------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO       |
| 2.a | Symptom:  | FEVER    |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.b | Symptom:  | FATIGUE  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.c | Symptom:  | HEADACHE |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                               |
|-----|--|-------------------------------|
| 2.d | Symptom:   | CHILLS                        |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.e | Symptom:   | VOMITING                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.f | Symptom:   | DIARRHEA                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.g | Symptom:   | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.h | Symptom:   | NEW OR WORSENERED JOINT PAIN  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 3.  | Injection Site Location:   | DELTOID MUSCLE                |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                        |
|-----|--|------------------------|
| 4.  | Injection Site Body Side:  | LEFT                   |
| 5.a | Injection Site Reaction:   | REDNESS                |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |
| 5.b | Injection Site Reaction:   | SWELLING               |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Sep/4/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |                       |             |
|-----|-----------------------|-------------|
| 2.a | Record Identifier:    | 1           |
|     | Temperature:          | [36.7]      |
|     | Unit:                 | C           |
|     | Temperature Location: | ORAL CAVITY |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Sep/4/2020   |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | NASAL_SWAB                               |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Sep/4/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPWXHT] |
|-----|-----------|----------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**eCRF Audit Trail History**

| <b>Vaccination</b> |   |   |
|--------------------|---|---|
| 1.                 | Was there a temporary delay of vaccination?   | NO  |
| 2.                 | Treatment Name  | [BLINDED THERAPY]                         |
| 3.                 | Formulation:  | INJECTION                                 |
| 4.                 | Dose Date Time:   | Sep/4/2020 09:19                          |
| 5.                 | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.                 | Body Side:  | LEFT                                      |
| 7.                 | Route:  | INTRAMUSCULAR                             |
| 8.                 | Actual Dose:  | [ ]                                       |
| 9.                 | Unit:   |   |
| 10.                | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11.                | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Oct/2/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |          |
|-----|---|----------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO       |
| 2.a | Symptom:  | FEVER    |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.b | Symptom:  | FATIGUE  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |
| 2.c | Symptom:  | HEADACHE |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO       |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                               |
|-----|--|-------------------------------|
| 2.d | Symptom:   | CHILLS                        |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.e | Symptom:   | VOMITING                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.f | Symptom:   | DIARRHEA                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.g | Symptom:   | NEW OR WORSENERED MUSCLE PAIN |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 2.h | Symptom:   | NEW OR WORSENERED JOINT PAIN  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO                            |
| 3.  | Injection Site Location:   | DELTOID MUSCLE                |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                        |
|-----|--|------------------------|
| 4.  | Injection Site Body Side:  | LEFT                   |
| 5.a | Injection Site Reaction:   | REDNESS                |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |
| 5.b | Injection Site Reaction:   | SWELLING               |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE |
|     | Were injection site reactions present on the last day the Subject Diary was completed? | NO                     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/2/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                      |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPVY6S] |
| 5.b | Sample ID | [BRXGCR] |
| 5.c | Sample ID | [BRXGCS] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/28/2020 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

|    |                         |         |
|----|-------------------------|---------|
| 3. | COVID-19 Illness Visit: | COVID_A |
|----|-------------------------|---------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date of Assessment:            | Dec/28/2020   |
| 2. | Date of First Symptom Started: | Dec/24/2020   |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Dec/29/2020 |

**Symptoms**

|     |                      |                                      |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms:            | FEVER                                |
|     | Was symptom present? | NO                                   |
| 4.b | Symptoms:            | NEW OR INCREASED COUGH               |
|     | Was symptom present? | YES                                  |
| 4.c | Symptoms:            | NEW OR INCREASED SHORTNESS OF BREATH |
|     | Was symptom present? | NO                                   |
| 4.d | Symptoms:            | CHILLS                               |
|     | Was symptom present? | NO                                   |
| 4.e | Symptoms:            | NEW OR INCREASED MUSCLE PAIN         |
|     | Was symptom present? | YES                                  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|                         |                        |                              |
|-------------------------|------------------------|------------------------------|
| 4.f                     | Symptoms:              | NEW LOSS OF TASTE OR SMELL   |
|                         | Was symptom present?   | NO                           |
| 4.g                     | Symptoms:              | NEW OR INCREASED SORE THROAT |
|                         | Was symptom present?   | YES                          |
| 4.h                     | Symptoms:              | DIARRHEA                     |
|                         | Was symptom present?   | NO                           |
| 4.i                     | Symptoms:              | VOMITING                     |
|                         | Was symptom present?   | NO                           |
| <b>Symptoms - Other</b> |                        |                              |
| 5.                      | Symptoms - Other Text: | [ ]                          |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance                   |
|----|--------------------|---------------|------------------------------|----------------------------|-------------|---------------------------------|
| 1. | Not Done           | Not Done      | Not Done                     | Not Done                   | Not Done    | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

|    |                               |                          |                          |
|----|-------------------------------|--------------------------|--------------------------|
| 1. | Actual Date of Collection:    | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 2. | Specimen Type:                | Not Done<br>_____        | <a href="#">Comments</a> |
| 3. | Specimen Collection Location: | Not Done<br>_____        | <a href="#">Comments</a> |
| 4. | Assay Code and Description:   | Not Done<br>_____        | <a href="#">Comments</a> |
| 5. | Device Type:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 6. | Trade Name:                   | Not Done<br>_____        | <a href="#">Comments</a> |
| 7. | Test Result:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 8. | Comments/Findings /Details:   | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 9. | Trade Name Other, Specify:    | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |                          |
|----|--|--------------------------|
| 1. | Data Origin  | SITE                     |
| 2. | Sample Type  | NASAL_SWAB_SELF          |
| 3. | Sample Collected?  | NO                       |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Subject used site swab] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411117**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[eCRF Audit Trail History](#)**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/28/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BR7963] |
|-----|-----------|----------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Health Care Utilization**

|     |                                       |                        |
|-----|---------------------------------------|------------------------|
| 1.a | Physician or Healthcare Professional: | SPECIALIST             |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.b | Physician or Healthcare Professional: | EMERGENCY ROOM         |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.d | Physician or Healthcare Professional: | URGENT CARE            |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
|     | Occurrence of Visits or Contacts:     | NO                     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |                                       |       |
|-----|---------------------------------------|-------|
| 1.f | Physician or Healthcare Professional: | OTHER |
|     | Occurrence of Visits or Contacts:     | NO    |

**Health Care Utilization Other**

|    |                                     |     |
|----|-------------------------------------|-----|
| 2. | Other Type of Practitioner Specify: | [ ] |
|----|-------------------------------------|-----|

**Health Care Utilization**

|    |  |    |
|----|--|----|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | NO |
|----|--|----|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance                   |
|----|----------------------|---------------------------------------|-----------|-----------|------------|---------------------------------|
| 1. |                      |                                       |           |           |            | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Respiratory Treatment**

|    |   |     |
|----|---|-----|
| 1. | What is the treatment Identifier?             | [ ] |
| 2. | Concomitant Non-drug Treatment Pre-specified: |     |
| 3. | Treatment:                                    |     |
| 4. | Treatment:                                    | [ ] |
| 5. | Start Date:                                   | //  |
| 6. | Ongoing?                                      |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Illness Details**

|    |  |                            |
|----|--|----------------------------|
| 1. | Category of Clinical Event:                              | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO                         |
| 3. | Toxicity Grade:  | 1                          |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance                   |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. |                             |                               |                    |                | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Illness Details**

|    |                                |  |
|----|--------------------------------|--|
| 1. | Category of Clinical Event:    |  |
| 2. | Subcategory of Clinical Event: |  |
| 3. | Was a diagnosis obtained?      |  |
| 4. | Toxicity Grade:                |  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |             |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Lab Chemistry Details**

|    |                             |     |
|----|-----------------------------|-----|
| 1. | Lab Panel:                  |     |
| 2. | Laboratory Name and Address | [ ] |
| 3. | Collection Date:            | //  |
| 4. | Specimen Type:              |     |

**Lab Result**

|    |             |                                   |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [ ]                               |
|    | Test:       |                                   |
|    | Result:     | [ ]                               |
|    | Not Done:   |                                   |
|    | LNMT        | Low<br>[ ]<br>High<br>[ ]<br>Unit |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category for Lab Test | Vendor Name (DERIVED) | Collection Date | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|-----------------------|-----------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |                       |                 |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Laboratory Data Hematology**

|    |                             |     |
|----|-----------------------------|-----|
| 1. | Lab Panel:                  |     |
| 2. | Laboratory Name and Address | [ ] |
| 3. | Collection Date:            | //  |
| 4. | Specimen Type:              |     |

**Lab Result**

|    |             |                                   |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [ ]                               |
|    | Test:       |                                   |
|    | Result:     | [ ]                               |
|    | Not Done:   |                                   |
|    | LNMT        | Low<br>[ ]<br>High<br>[ ]<br>Unit |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date: | Vital Signs Details       |                  |                   | Form Instance                   |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. |       | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Vital Signs**

|    |       |    |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

**Vital Signs Details**

|    |  |     |
|----|--|-----|
| 2. | Record Identifier:                       |     |
|    | Systolic:                                | [ ] |
|    | Diastolic:                               | [ ] |
|    | Respiratory Rate in respirations/minute: | [ ] |
|    | Heart Rate in beats/minute:              | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date: | Vital Signs Details       |                          | Form Instance                   |
|----|-------|---------------------------|--------------------------|---------------------------------|
| 1. |       | <b>Record Identifier:</b> | <b>Oxygen Saturation</b> | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Vital Signs**

|    |       |    |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

**Vital Signs Details**

|    |                       |     |
|----|-----------------------|-----|
| 2. | Record Identifier:    |     |
|    | SPO2 Pulse Oximetry % | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. |                         |                           |                                   | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Oxygenation Parameters**

|    |                                    |     |
|----|------------------------------------|-----|
| 1. | Date Time of Assessment:           | //  |
| 2. | Arterial Blood Gases PaO2 (mmHg):  | [ ] |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. |                            |                         |                                       |                    |            | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

|    |   |     |
|----|---|-----|
| 1. | What is the medication identifier?  | [ ] |
| 2. | Category:   |     |
| 3. | Concomitant Medications Pre-specified:  |     |
| 4. | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5. | Start Date:   | //  |
| 6. | Ongoing?  |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance                   |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. |                    |                        |                |                    | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Imaging**

|    |                         |    |
|----|-------------------------|----|
| 1. | Date of Assessment:     | // |
| 2. | Location of Assessment: |    |
| 3. | Type of Imaging Exam:   |    |
| 4. | Assessment:             |    |

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/25/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

|    |                         |          |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_A1 |
|----|-------------------------|----------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/25/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPTKX2] |
| 5.b | Sample ID | [BSCYXY] |
| 5.c | Sample ID | [BSCYXZ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
Visit

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit    **Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04    **Form Status:** Not Started

**Site No:** 1241    **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 19:09

**Unplanned Assessments**

|    |             |  |
|----|-------------|--|
| 1. | Assessments |  |
|----|-------------|--|

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Oct/2/2020  |
| 2. | Phase of Disposition:                      | VACCINATION |
| 3. | Status:                                    | COMPLETED   |
| 4. | Specify Status:                            | [ ]         |

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Follow-Up**

|    |  |     |
|----|--|-----|
| 1. | Date of Completion/Discontinuation/Death : | //  |
| 2. | Phase of Disposition:                      |     |
| 3. | Status:                                    |     |
| 4. | Specify Status:                            | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**COVID-19 Repeat Swab**

|    |                       |  |
|----|-----------------------|--|
| 3. | COVID-19 Repeat Swab: |  |
|----|-----------------------|--|

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

|    |  |     |
|----|--|-----|
| 1. | Data Origin  |     |
| 2. | Sample Type  |     |
| 3. | Sample Collected?  |     |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ] |

**Aliquot**

Please enter barcode for each aliquot.

|    |           |     |
|----|-----------|-----|
| 5. | Sample ID | [ ] |
|----|-----------|-----|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category      | AE Identifier | Adverse Event       | Start Date              | Is the Adverse Event Still Ongoing                 | Form Instance                   |
|----|---------------|---------------|---------------------|-------------------------|--|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Myalgia             | Jan/30/2021 U<br>NK:UNK | NO<br>End Date Time:<br><br>Feb/2/2021 UNK:U<br>NK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | Injection site pain | Jan/30/2021 U<br>NK:UNK | NO<br>End Date Time:<br><br>Feb/2/2021 UNK:U<br>NK | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Adverse Event Report**

|    |  |  |
|----|--|--|
| 1. | Category:  | ADVERSE EVENT                              |
| 2. | AE ID:   | [1]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms) | [Myalgia]                                  |
| 4. | Start Date Time:   | Jan/30/2021 UNK:UNK                        |
| 5. | Is the adverse event still ongoing?  | NO<br>End Date Time:<br>Feb/2/2021 UNK:UNK |
| 6. | Toxicity Grade:  | 1  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |   |                |
|-----|---|----------------|
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO             |
| 8.  | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO             |
| 9.  | Is this event related to study treatment:   | RELATED        |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given?   | YES            |
| 12. | Was a Non-Drug Treatment given?   | NO             |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                    |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                 |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [ ]                |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

### Adverse Event Report

|    |  |  |
|----|--|--|
| 1. | Category:  | ADVERSE EVENT                              |
| 2. | AE ID:   | [2]  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms) | [Injection site pain]                      |
| 4. | Start Date Time:   | Jan/30/2021 UNK:UNK                        |
| 5. | Is the adverse event still ongoing?  | NO<br>End Date Time:<br>Feb/2/2021 UNK:UNK |
| 6. | Toxicity Grade:  | 1  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |   |                |
|-----|---|----------------|
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | NO             |
| 8.  | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO             |
| 9.  | Is this event related to study treatment:   | RELATED        |
| 10. | Latest Action Taken with Study Treatment:   | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given?   | NO             |
| 12. | Was a Non-Drug Treatment given?   | NO             |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|     |  |                    |
|-----|--|--------------------|
| 13. | What was the outcome of this adverse event?:                               | RECOVERED/RESOLVED |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                 |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [ ]                |

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance                   |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. |          |                  |            |                                       |                                | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Medication Error**

|     |   |     |
|-----|---|-----|
| 1.  | Category:   |     |
| 2.  | Medication Error (Type of Medication Error):                                  | [ ] |
| 3.  | Start Date:   | //  |
| 4.  | Is the medication error still ongoing?  |     |
| 5.  | Latest Action Taken with Study Treatment:                                     |     |
| 6.  | Was a Concomitant Medication given?   |     |
| 7.  | Was a Non-Drug Treatment given?   |     |
| 8.  | Did the Medication Error cause the subject to be discontinued from the study? |     |
| 9.  | Was this medication error associated with any adverse events?                 |     |
| 10. | Serious Adverse Event Number: For Pfizer Use Only                             | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. |                            |                         |                                       |                    |            | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

|    |  |     |
|----|--|-----|
| 1. | What is the medication identifier?   | [ ] |
| 2. | Category:  |     |
| 3. | Concomitant Medications Pre-specified:   |     |
| 4. | <p>Medication:</p> <p>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).</p> | [ ] |
| 5. | Date:  | //  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. |                            |                         |                                       |                    |                  | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications Pre-specified:  |     |
| 4.  | Medication:<br><br>Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [ ] |
| 5.  | Dose:   | [ ] |
| 6.  | Dose Unit:  |     |
| 7.  | Dose Frequency:   |     |
| 8.  | Route:  |     |
| 9.  | Start Date:   | //  |
| 10. | Ongoing?  |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance                   |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. |          |                      |                                       |           |            | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Radiation Treatment**

|    |   |     |
|----|---|-----|
| 1. | Category:                                     |     |
| 2. | What is the treatment Identifier?             | [ ] |
| 3. | Concomitant Non-drug Treatment Pre-specified: |     |
| 4. | Treatment:                                    | [ ] |
| 5. | Start Date:                                   | //  |
| 6. | Ongoing?                                      |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| #  | Transfusion Type | Date of Transfusion | Form Instance                   |
|----|------------------|---------------------|---------------------------------|
| 1. |                  |                     | <a href="#">Repeating Pages</a> |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

|    |                      |    |
|----|----------------------|----|
| 1. | Transfusion Type:    |    |
| 2. | Date of Transfusion: | // |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

|    |       |    |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

**Vital Signs Details**

|    |                       |     |
|----|-----------------------|-----|
| 2. | Record Identifier:    |     |
|    | Temperature:          | [ ] |
|    | Unit:                 |     |
|    | Temperature Location: |     |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Lab Urinalysis**

|    |                                       |     |
|----|---------------------------------------|-----|
| 1. | Lab Panel:                            |     |
| 2. | Lab Sub-Panel:                        |     |
| 3. | Collection Date:                      | //  |
| 4. | Laboratory Name and Address (Derived) | [ ] |
| 5. | Specimen Type:                        |     |

**Lab Result**

|    |             |     |
|----|-------------|-----|
| 6. | Sponsor ID: | [ ] |
|    | Test:       |     |
|    | Result:     |     |
|    | Not Done:   |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vaccination**

|     |   |     |
|-----|---|-----|
| 1.  | Was there a temporary delay of vaccination?   |     |
| 2.  | Treatment Name  | [ ] |
| 3.  | Formulation:  |     |
| 4.  | Dose Date Time:   | //  |
| 5.  | Anatomical Location:  |     |
| 6.  | Body Side:  |     |
| 7.  | Route:  |     |
| 8.  | Actual Dose:  | [ ] |
| 9.  | Unit:   |     |
| 10. | Timeframe Subject Was Observed  |     |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? |     |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

| Date of Visit |                 |             |
|---------------|-----------------|-------------|
| 1.            | Date of Visit   | Jan/27/2021 |
| 2.            | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION  
Unscheduled

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response<br>- Is participant willing to<br>return for Vaccination 3? | Participant is willing to return for Vaccination 3<br><br>Participant is:<br>eligible per local/national recommendations and confirmed to<br>have received only placebo at Vaccination 1/2 |
|----|---|--|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Jan/27/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Withdrawal Of Consent**

|    |                                 |    |
|----|---------------------------------|----|
| 1. | Withdrawal of Consent<br>Date : | // |
|----|---------------------------------|----|

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Death Details**

|    |   |    |
|----|---|----|
| 1. | Date of Collection / Notification of Death: | // |
|----|---|----|

**Cause of Death**

|    |                        |     |
|----|------------------------|-----|
| 2. | Cause of Death Status: |     |
|    | Cause of Death:        | [ ] |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/29/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Jan/29/2021 |
|----|--------------|--|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Form Comments](#)

**Inclusion Criteria Not Met**

|    |  |                         |
|----|--|-------------------------|
| 1. | Description of Inclusion Criterion Not Met | Not Applicable<br>_____ |
|----|--|-------------------------|

**Exclusion Criteria Met**

|    |  |                         |
|----|--|-------------------------|
| 2. | Description of Exclusion Criterion Met | Not Applicable<br>_____ |
|----|--|-------------------------|

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

|    |  |                    |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Jan/29/2021        |
| 2. | Phase of Disposition:                      | REPEAT SCREENING 1 |
| 3. | Status:                                    | COMPLETED          |
| 4. | Specify Status:                            | [ ]                |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Jan/29/2021  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/29/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BR6GWL] |
| 5.b | Sample ID | [BSD7F0] |
| 5.c | Sample ID | [BSD7F1] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/29/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BR6GW2] |
|-----|-----------|----------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                   |
|-----|---|-------------------|
| 1.  | Was there a temporary delay of vaccination?   | NO                |
| 2.  | Treatment Name  | [BNT162b2]        |
| 3.  | Formulation:  | INJECTION         |
| 4.  | Dose Date Time:   | Jan/29/2021 09:47 |
| 5.  | Anatomical Location:  | DELTOID MUSCLE    |
| 6.  | Body Side:  | LEFT              |
| 7.  | Route:  | INTRAMUSCULAR     |
| 8.  | Actual Dose:  | [30.0]            |
| 9.  | Unit:   | ug                |
| 10. | Timeframe Subject Was Observed  | 30 MINUTES        |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES               |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Feb/19/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

|    |                                       |              |
|----|---------------------------------------|--------------|
| 1. | Lab Panel:                            | URINALYSIS   |
| 2. | Lab Sub-Panel:                        | PREGNANCY    |
| 3. | Collection Date:                      | Feb/19/2021  |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type:                        | URINE        |

**Lab Result**

|     |             |                               |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113]                         |
|     | Test:       | Choriogonadotropin Beta_PX113 |
|     | Result:     |                               |
|     | Not Done:   | NOT DONE                      |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Feb/19/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BRKFF0] |
|-----|-----------|----------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                   |
|-----|---|-------------------|
| 1.  | Was there a temporary delay of vaccination?   | NO                |
| 2.  | Treatment Name  | [BNT162b2]        |
| 3.  | Formulation:  | INJECTION         |
| 4.  | Dose Date Time:   | Feb/19/2021 09:50 |
| 5.  | Anatomical Location:  | DELTOID MUSCLE    |
| 6.  | Body Side:  | LEFT              |
| 7.  | Route:  | INTRAMUSCULAR     |
| 8.  | Actual Dose:  | [30.0]            |
| 9.  | Unit:   | ug                |
| 10. | Timeframe Subject Was Observed  | 30 MINUTES        |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES               |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

|    |                 |    |
|----|-----------------|----|
| 1. | Date of Visit   | // |
| 2. | Erroneous Visit |    |

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

|    |                   |     |
|----|-------------------|-----|
| 1. | Contact Type:     |     |
| 2. | Was contact made? |     |
| 3. | Comments:         | [ ] |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Treatment**

|    |   |     |
|----|---|-----|
| 1. | Date of Completion/Discontinuation /Death : | //  |
| 2. | Phase of Disposition:                       |     |
| 3. | Status:                                     |     |
| 4. | Specify Status:                             | [ ] |

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |            |
|----|---------------------|------------|
| 1. | Subject Status      | FOLLOW-UP  |
| 2. | Subject Status Date | Oct/2/2020 |

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

|    |                    |                      |
|----|--------------------|----------------------|
| 1. | Casebook Signature | Click Here to Enable |
|----|--------------------|----------------------|

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name    | Signature Meaning | Date   | Type | Action |
|---------|-------------------|--|------|--------|
| (b) (6) | Approved          | Feb-24-2021 12:09:23 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment                                     |
|------|--|------------------|---|
| 6.a  | Aug-14-2020 11:53:19 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject has no potential to become pregnant |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment                                     |
|------|--|------------------|---|
| 6.a  | Aug-14-2020 11:53:19 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject has no potential to become pregnant |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment                                     |
|------|--|------------------|---|
| 6.a  | Aug-14-2020 11:53:19 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject has no potential to become pregnant |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| Form | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| Form | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| Form | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 1    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 1    | Jan-21-2021 09:53:59 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 1    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| 1    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 2    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 2    | Jan-21-2021 09:54:12 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 2    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 2    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 3    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 3    | Jan-21-2021 09:54:25 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 3    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| 3    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 4    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 4    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| 4    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 5    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 5    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| 5    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 6    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 6    | Jan-21-2021 09:54:37 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 6    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 6    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 7    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 7    | Jan-21-2021 09:54:48 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 7    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 7    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 8    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 8    | Jan-21-2021 09:55:05 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 8    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 8    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment  |
|------|--|------------------|--|
| 9    | Jan-21-2021 09:55:36 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 9    | Jan-21-2021 09:55:17 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |
| 9    | Jan-21-2021 09:53:39 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab                   |
| 9    | Jan-15-2021 12:30:02 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Subject refused to perform the exam at the local lab<br><hr/> Not Done |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Item | Date   | User             | Comment        |
|------|--|------------------|----------------|
| Form | Jan-29-2021 12:03:44 (UTC-03:00)<br>City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospite Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

| Name    | Signature Meaning | Date   | Type | Action |
|---------|-------------------|--|------|--------|
| (b) (6) | Approved          | Feb-24-2021 12:09:23 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Feb-19-2021 10:10:30 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |  |      |        |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Feb-04-2021 16:44:00 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

By my dated signature below, I, (b) (6), verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Jan-29-2021 12:02:34 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|                  |          |  |      |        |
|------------------|----------|--|------|--------|
| Edson<br>Moreira | Approved | Jan-27-2021 13:05:58 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, EdsonMoreira, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Jan-25-2021 09:59:50 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|                  |          |  |      |        |
|------------------|----------|--|------|--------|
| Edson<br>Moreira | Approved | Jan-21-2021 17:15:30 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, EdsonMoreira, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Dec-28-2020 11:26:37 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |  |      |        |
|---------|----------|--|------|--------|
| (b) (6) | Approved | Oct-20-2020 17:38:52 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|---------|----------|--|------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Oct-20-2020 16:46:27 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|                  |          |  |      |        |
|------------------|----------|--|------|--------|
| Edson<br>Moreira | Approved | Oct-13-2020 20:20:21 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, EdsonMoreira, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|         |     |  |  |   |
|---------|-----|--|--|---|
| (b) (6) | N/A | Oct-02-2020 15:53:36 (UTC-03:00)<br>City of Buenos Aires |  | Edit - All<br>signatures<br>invalidated |
|---------|-----|--|--|---|

**Affidavit:**

N/A

|                  |          |  |      |        |
|------------------|----------|--|------|--------|
| Edson<br>Moreira | Approved | Sep-16-2020 18:53:33 (UTC-03:00)<br>City of Buenos Aires | BOOK | Signed |
|------------------|----------|--|------|--------|

**Affidavit:**

By my dated signature below, I, EdsonMoreira, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - Protocol version*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:45:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>30 JUN 2020 | Initial Entry |

*2. Select appropriate response - What cohort does the subject belong to?*

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Aug-14-2020<br>11:45:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Consent Was:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Con-<br>sent Obtained<br><br>Aug/14/2020 | Initial Entry |

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason                               |
|--|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Aug-14-2020<br>11:45:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12411117 | Item copied<br>from previous<br>form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                             | Reason              |
|--|-----------------|-------------------------|-----------------------------------|---------------------|
| Aug-14-2020<br>11:45:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)1953 | Enrollment<br>Entry |

**3. Sex:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-14-2020<br>11:46:16<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:16<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT HISPANIC OR<br>LATINO(A) OR OF | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

SPANISH ORIGIN

**5. Race: (Check X all that apply):**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:16<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BLACK OR AFRIC<br>AN AMERICAN | Initial Entry |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:46:25<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*I.a*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Incl 1</b><br><b>usio</b><br><b>n N</b><br><b>um</b><br><b>ber:</b><br><b>Crit Male or female</b><br><b>erio participants bet</b><br><b>n D ween the ages</b><br><b>escr of 18 and 55 ye</b><br><b>ipti ars, inclusive, 6</b><br><b>on: 5 and 85 years,</b><br><b>inclusive, or 18</b><br><b>and 85 years, i</b><br><b>nclusive, at ran</b><br><b>domization (de</b><br><b>pendent upon s</b><br><b>tudy stage)</b><br><b>Crit YES</b><br><b>erio</b><br><b>n m</b><br><b>et?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Crit IN01A00<br/>erion I<br/>D: (For<br/>Pfizer<br/>er use<br/>only)</b><br>: |  |
|--|--|--|--|--|

***1.a Inclusion Number:***

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>1 | Initial Entry |

***1.a Criterion Description:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.a Criterion met?***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.a Criterion ID: (For Pfizer use only)***

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>IN01A00 | Initial Entry |

***1.b***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Incl 2<br>usio<br>n N<br>umb<br>er: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <p><b>Crit</b> Participants w<br/><b>erio</b> ho are willing<br/><b>n De</b> and able to co<br/><b>scri</b> mply with all s<br/><b>ptio</b> cheduled visits<br/><b>n:</b> , vaccination pl<br/>an, laboratory t<br/>ests, lifestyle c<br/>onsiderations,<br/>and other study<br/>procedures</p> <p><b>Crit</b> YES<br/><b>erio</b><br/><b>n m</b><br/><b>et?:</b></p> <p><b>Crit</b> IN02A00<br/><b>erio</b><br/><b>n ID</b><br/><b>: (Fo</b><br/><b>r Pfi</b><br/><b>zer</b><br/><b>use</b><br/><b>only</b><br/><b>):</b></p> |  |
|--|--|--|--|--|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**1.b Inclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Participants who are<br>willing and able to co<br>mply with all schedul<br>ed visits, vaccination<br>plan, laboratory tests,<br>lifestyle consideratio<br>ns, and other study pr<br>ocedures | Initial Entry |

**1.b Criterion met?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.b Criterion ID: (For Pfizer use only)**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>IN02A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

*I.c*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Incl 3</b><br><b>usio</b><br><b>n N</b><br><b>umb</b><br><b>er:</b><br><b>Crit</b> Healthy partici<br><b>erio</b> pants who are<br><b>n De</b> determined by<br><b>scri</b> medical history<br><b>ptio</b> , physical exa<br><b>n:</b> mination, and c<br>linical judge<br>nt of the invest<br>igator to be eli<br>gible for inclus<br>ion in the study<br><br><b>Crit</b> YES<br><b>erio</b><br><b>n m</b><br><b>et?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Crit IN03A00<br/>erio<br/>n ID<br/>: (F<br/>or P<br/>fizer<br/>use<br/>only<br/>):</b> |  |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

***I.c Inclusion Number:***

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>3 | Initial Entry |

***I.c Criterion Description:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Healthy participants<br>who are determined b<br>y medical history, ph<br>ysical examination, a<br>nd clinical judgment<br>of the investigator to<br>be eligible for inclusi<br>on in the study | Initial Entry |

***I.c Criterion met?***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

***I.c Criterion ID: (For Pfizer use only)***

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>IN03A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

*1.d*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Incl 4</b><br><b>usio</b><br><b>n N</b><br><b>umb</b><br><b>er:</b><br><b>Crit</b> Capable of giv<br><b>erio</b> ing personal si<br><b>n De</b> gned informed<br><b>scri</b> consent, which<br><b>ptio</b> includes compl<br><b>n:</b> iance with the<br>requirements a<br>nd restrictions<br>listed in the IC<br>D and in this p<br>rotocol<br><br><b>Crit</b> YES<br><b>erio</b><br><b>n m</b><br><b>et?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Crit IN04A00<br/>erio<br/>n ID<br/>: (Fo<br/>r Pfi<br/>zer<br/>use<br/>only<br/>):</b> |  |
|--|--|--|---|--|

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History**Form Version:** 30-Jul-2020 21:27**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411117**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09***1.d Inclusion Number:***

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>4 | Initial Entry |

***1.d Criterion Description:***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Capable of giving per<br>sonal signed informe<br>d consent, which incl<br>udes compliance with<br>the requirements and<br>restrictions listed in t<br>he ICD and in this pr<br>otocol | Initial Entry |

***1.d Criterion met?***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

***1.d Criterion ID: (For Pfizer use only)***

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>IN04A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Excl 1<br>usio<br>n N<br>umb<br>er:<br>Crit Other medical<br>erio or psychiatric c<br>n De ondition incl. r<br>scri ecent (within p<br>ptio ast year) or acti<br>n: ve suicidal idea<br>tion/behavior/l<br>ab abnormality<br>that may increa<br>se the risk of st<br>udy participati<br>on<br>Crit NO<br>erio<br>n m<br>et?: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Crit EX01A00<br/>erion ID<br/>: (F<br/>or P<br/>fizer<br/>use<br/>only<br/>):</b> |  |
|--|--|--|--|--|

**2.a Exclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Other medical or psy<br>chiatric condition incl<br>. recent (within past y<br>ear) or active suicidal<br>ideation/behavior/lab<br>abnormality that may<br>increase the risk of st<br>udy participation | Initial Entry |

**2.a Criterion met?**

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

*2.a Criterion ID: (For Pfizer use only)*

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX01A00 | Initial Entry |

*2.b*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Excl 2<br>usion<br>Num<br>ber:<br>Crite Known infecti<br>rion on with huma<br>Desc n immunodef<br>riptionciency virus (<br>n: HIV), hepatiti<br>s C virus (HC<br>V), or hepatiti<br>s B virus (HB<br>V) | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Crite NO<br/>rion<br/>met?<br/>:<br/>Crite EX02A00<br/>rion I<br/>D: (F<br/>or Pfi<br/>zer u<br/>se onl<br/>y):</b> |  |
|--|--|--|--|--|

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.b Exclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>2 | Initial Entry |

**2.b Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Known infection with<br>human immunodeficiency<br>virus (HIV), hepatitis<br>C virus (HCV),<br>or hepatitis B virus (HBV) | Initial Entry |

**2.b Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b Criterion ID: (For Pfizer use only)**

| Date                    | Location        | User                | Value                         | Reason        |
|-------------------------|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56 | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX02A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City  
of Buenos Aires

(b) (4), (b) (6)

2.c

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Excl 3</b><br><b>usio</b><br><b>n N</b><br><b>umb</b><br><b>er:</b><br><b>Crit</b> History of severe<br><b>erio</b> re adverse reac<br><b>n De</b> tion associated<br><b>scri</b> with a vaccine<br><b>ptio</b> and/or severe a<br><b>n:</b> llergic reaction<br>(eg, anaphylax<br>is) to any com<br>ponent of the s<br>tudy interventi<br>on(s)<br><br><b>Crit</b> NO<br><b>erio</b><br><b>n m</b><br><b>et?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Crit EX03A00<br/>erion ID<br/>: (For Pfizer<br/>use only<br/>):</b> |  |
|--|--|--|--|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.c Exclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>3 | Initial Entry |

**2.c Criterion Description:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>History of severe adverse reaction associated with a vaccine and /or severe allergic reaction (eg, anaphylaxis ) to any component of the study intervention (s) | Initial Entry |

**2.c Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.c Criterion ID: (For Pfizer use only)**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX03A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

**2.d**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br>4<br><b>Criterion Description:</b> Receipt of medication is intended to prevent COVID-19<br><b>Criterion met?:</b> NO<br><b>Criterion ID: (Formerly):</b> EX04A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.d Exclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>4 | Initial Entry |

**2.d Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Receipt of medication<br>s intended to prevent<br>COVID-19 | Initial Entry |

**2.d Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.d Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX04A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.e

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Excl 8</b><br><b>usio</b><br><b>n Nu</b><br><b>mbe</b><br><b>r:</b><br><b>Crit Immunocompr</b><br><b>erio omised individ</b><br><b>n De uals with kno</b><br><b>scrip wn or suspecte</b><br><b>tion: d immunodef</b><br><b>ciency, as dete</b><br><b>rmined by hist</b><br><b>ory and/or lab</b><br><b>oratory/physic</b><br><b>al examination</b><br><br><b>Crit NO</b><br><b>erio</b><br><b>n me</b><br><b>t?:</b><br><b>Crit EX08A00</b><br><b>erio</b><br><b>n ID</b><br><b>: (Fo</b><br><b>r Pfi</b><br><b>zer u</b><br><b>se on</b><br><b>ly):</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.e Exclusion Number:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>8 | Initial Entry |

**2.e Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Immunocompromised<br>individuals with kno<br>wn or suspected imm<br>unodeficiency, as dete<br>rmined by history and<br>/or laboratory/physica<br>l examination | Initial Entry |

**2.e Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.e Criterion ID: (For Pfizer use only)**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX08A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.f

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Excl 10<br>usio<br>n Nu<br>mbe<br>r:<br>Crit Bleeding diath<br>erio esis or conditio<br>n De n associated wi<br>scri th prolonged bl<br>ptio eeding that wo<br>n: uld, in the opin<br>ion of the inve<br>stigator, contra<br>indicate intram<br>uscular injecti<br>on<br>Crit NO<br>erio<br>n me<br>t?: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Crit EX10A00</b><br><b>erio</b><br><b>n ID</b><br><b>: (Fo</b><br><b>r Pfi</b><br><b>zer</b><br><b>use</b><br><b>only</b><br><b>):</b> |  |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.f Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>10 | Initial Entry |

**2.f Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Bleeding diathesis or<br>condition associated<br>with prolonged bleedi<br>ng that would, in the<br>opinion of the investi<br>gator, contraindicate i<br>ntramuscular injectio<br>n | Initial Entry |

**2.f Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.f Criterion ID: (For Pfizer use only)**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX10A00 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

2.g

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Exclusio</b> 11<br><b>n Numb</b><br><b>er:</b><br><b>Criteria</b> Women w<br><b>n Descri</b> ho are pre<br><b>ption:</b> gnant or b<br>reastfeedi<br>ng<br><b>Criteria</b> NO<br><b>n met?:</b><br><b>Criteria</b> EX11A00<br><b>n ID: (F</b><br><b>or Pfizer</b><br><b>use only)</b><br>: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.g Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>11 | Initial Entry |

**2.g Criterion Description:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Women who are preg<br>nant or breastfeeding | Initial Entry |

**2.g Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.g Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX11A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.h**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br><b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine<br><b>Criterion met?:</b><br><b>Criterion ID: (For Pfizer use only):</b> EX12A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.h Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>12 | Initial Entry |

**2.h Criterion Description:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Previous vaccination<br>with any coronavirus<br>vaccine | Initial Entry |

**2.h Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.h Criterion ID: (For Pfizer use only)**

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX12A00 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

2.i

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Exclu 13</b><br><b>sion</b><br><b>Num</b><br><b>ber:</b><br><b>Crite</b> Subjects who<br><b>tion</b> receive immu<br><b>Descr</b> nosuppressive<br><b>ption</b> therapy, such<br><b>:</b> as cytotoxic a<br>gents or syste<br>mic corticoste<br>roids<br><b>Crite</b> NO<br><b>tion</b><br><b>met?:</b><br><b>Crite</b> EX13A01<br><b>tion I</b><br><b>D: (F</b><br><b>or Pfi</b><br><b>zer us</b><br><b>e only</b><br><b>):</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.i Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>13 | Initial Entry |

**2.i Criterion Description:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Subjects who receive<br>immunosuppressive t<br>herapy, such as cyto<br>xic agents or systemi<br>c corticosteroids | Initial Entry |

**2.i Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.i Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                | Value                         | Reason        |
|---|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX13A01 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

2.j

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Excl 15</b><br><b>usio</b><br><b>n Nu</b><br><b>mbe</b><br><b>r:</b><br><b>Crit</b> Receipt of blo<br><b>erio</b> od/plasma pro<br><b>n De</b> ducts or immu<br><b>scrip</b> noglobulin, fro<br><b>tion:</b> m 60 days bef<br>ore study inter<br>vention admini<br>stration or plan<br>ned receipt thr<br>oughout the st<br>udy<br><b>Crit</b> NO<br><b>erio</b><br><b>n me</b><br><b>t?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Crit EX14A01<br/>erio<br/>n ID<br/>: (Fo<br/>r Pfi<br/>zer<br/>use<br/>only<br/>):</b> |  |
|--|--|--|---|--|

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.j Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>15 | Initial Entry |

**2.j Criterion Description:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study | Initial Entry |

**2.j Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.j Criterion ID: (For Pfizer use only)**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX14A01 | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

2.k

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Excl 16</b><br><b>usio</b><br><b>n Nu</b><br><b>mbe</b><br><b>r:</b><br><b>Crite</b> Participation i<br><b>riou</b> n other studie<br><b>Desc</b> s involving st<br><b>ripti</b> udy interventi<br><b>on:</b> on within 28<br>days prior to s<br>tudy entry and<br>/or during stu<br>dy participati<br>on<br><b>Crite</b> NO<br><b>riou</b><br><b>met?</b><br>:<br><b>Crite</b> EX15A01<br><b>riou</b><br><b>ID:</b> (<br><b>For</b><br><b>Pfize</b><br><b>r use</b><br><b>only)</b><br>: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.k Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>16 | Initial Entry |

**2.k Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Participation in other<br>studies involving stu<br>dy intervention withi<br>n 28 days prior to stu<br>dy entry and/or durin<br>g study participation | Initial Entry |

**2.k Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.k Criterion ID: (For Pfizer use only)**

| Date                    | Location        | User                | Value                         | Reason        |
|-------------------------|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56 | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX15A01 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |                  |
|----------------------------------|------------------|
| (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) |
|----------------------------------|------------------|

2.1

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Exclusion Number:</b><br><b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles<br><b>Criterion met?:</b> NO<br><b>Criterion ID: (For Pfizer use only):</b> EX16A01 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.1 Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>17 | Initial Entry |

**2.1 Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Previous participatio<br>n in other studies inv<br>olving study interven<br>tion containing lipid<br>nanoparticles | Initial Entry |

**2.1 Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.1 Criterion ID: (For Pfizer use only)**

| Date  | Location        | User                | Value                         | Reason        |
|---|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX16A01 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                 |  |  |  |  |
|-----------------|--|--|--|--|
| of Buenos Aires |  |  |  |  |
|-----------------|--|--|--|--|

**2.m**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Excl 22</b><br><b>usio</b><br><b>n N</b><br><b>um</b><br><b>ber:</b><br><b>Crit</b> Investigator sit<br><b>erio</b> e staff or Pfize<br><b>n D</b> r employees di<br><b>escr</b> rectly involved<br><b>ipti</b> in the conduct<br><b>on:</b> of the study, sit<br>e staff otherwi<br>se supervised b<br>y the investigat<br>or, and their re<br>spective famil<br>y members<br><br><b>Crit</b> NO<br><b>erio</b><br><b>n m</b><br><b>et?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Crit EX21A01<br/>erion ID<br/>: (F<br/>or P<br/>fize<br/>r us<br/>e on<br/>ly):</b> |  |
|--|--|--|--|--|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**2.m Exclusion Number:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>22 | Initial Entry |

**2.m Criterion Description:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Investigator site staff<br>or Pfizer employees<br>directly involved in t<br>he conduct of the stu<br>dy, site staff otherwis<br>e supervised by the i<br>nvestigator, and their<br>respective family me<br>mbers | Initial Entry |

**2.m Criterion met?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.m Criterion ID: (For Pfizer use only)**

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF  
Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Aug-14-2020<br>11:46:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EX21A01 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:47:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-14-2020<br>11:47:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Aug-14-2020<br>11:47:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1.a*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Aug-14-2020<br>11:48:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH 1</b><br><b>Number:</b><br><b>Medical History Term:</b> Systemic arterial hypertension<br><b>Start Date:</b> UNK/UNK /1993<br><b>Ongoing:</b> YES | Initial Entry |

*1.a Line/MH Number:*

| Date  | Location        | User                | Value              | Reason  |
|---|-----------------|---------------------|--------------------|---|
| Oct-23-2020<br>11:25:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Deleted   | Query is invalid or does not apply  |
| Oct-20-2020<br>15:51:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Candidate | DM: site request to unlock page. Do not issue query. After updates are made and coding complete the |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                      |                         |                        |
|---|-----------------|----------------------|-------------------------|------------------------|
|   |                 |                      |                         | page can be re-locked. |
| Aug-14-2020<br>11:48:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>1 | Initial Entry          |

***1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-14-2020<br>11:48:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Systemic arterial hypertension | Initial Entry |

***1.a Start Date:***

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-14-2020<br>11:48:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/1993 | Initial Entry |

***1.a Ongoing:***

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-14-2020<br>11:48:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.b***

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-14-2020<br>11:49:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH N 2</b><br><b>umber:</b><br><b>Medical His</b> Osteoart<br><b>tory Term:</b> hritis<br><b>Start Date:</b> UNK/U<br>NK/200<br>5<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**1.b Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-14-2020<br>11:49:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Aug-14-2020<br>11:49:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Osteoarthritis | Initial Entry |

**1.b Start Date:**

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-14-2020<br>11:49:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2005 | Initial Entry |

**1.b Ongoing:**

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-14-2020<br>11:49:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

*I.c*

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Aug-14-2020<br>11:49:49<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 3<br><b>Number:</b><br><b>Medical History Term:</b> Benign thyroid nodules<br><b>Start Date:</b> Oct/UNK/2016<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.c Line/MH Number:***

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-14-2020<br>11:49:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

***1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-14-2020<br>11:49:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Benign thyroid nodules | Initial Entry |

***1.c Start Date:***

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-14-2020<br>11:49:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/UNK/2016 | Initial Entry |

***1.c Ongoing:***

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Aug-14-2020<br>11:49:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

*1.d*

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Aug-14-2020<br>13:14:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 4<br><b>Number:</b><br><b>Medical History Term:</b> Hysterectomy<br><b>Start Date:</b> UNK/UNK/2006<br><b>Ongoing:</b> NO<br><b>End Date:</b><br>UNK/UNK/2006 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**1.d Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-14-2020<br>13:14:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-14-2020<br>13:14:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Hysterectomy | Initial Entry |

**1.d Start Date:**

| Date  | Location        | User             | Value                              | Reason        |
|---|-----------------|------------------|------------------------------------|---------------|
| Aug-14-2020<br>13:14:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2006 | Initial Entry |

**1.d Ongoing:**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-14-2020<br>13:14:29<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2006 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

*I.e*

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-20-2020<br>16:46:27<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH N 5</b><br><b>umber:</b><br><b>Medical His</b> allergic r<br><b>tory Term:</b> hinitis<br><b>Start Date:</b> UNK/U<br>NK/200<br>0<br><b>Ongoing:</b> YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.e Line/MH Number:***

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-20-2020<br>16:46:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

***1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-20-2020<br>16:46:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>allergic rhinitis | Initial Entry |

***1.e Start Date:***

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-20-2020<br>16:46:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2000 | Initial Entry |

***1.e Ongoing:***

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-20-2020<br>16:46:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date:**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>77.1 | Initial Entry |

**3. Unit:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

| Date                    | Location        | User             | Value                       | Reason        |
|-------------------------|-----------------|------------------|-----------------------------|---------------|
| Aug-14-2020<br>11:50:19 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>151.5 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |                  |  |  |
|----------------------------------|------------------|--|--|
| (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) |  |  |
|----------------------------------|------------------|--|--|

5. Unit:

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Aug-14-2020 11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>cm | Initial Entry |

6. Body Mass Index:

| Date   | Location        | User                 | Value                      | Reason        |
|--|-----------------|----------------------|----------------------------|---------------|
| Aug-14-2020 11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>33.6 | Initial Entry |

7.a

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Aug-14-2020 11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b><br><b>Temperature:</b><br><b>Temperature Unit:</b><br><b>Temperature Location:</b><br><b>:: Y</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**7.a Record Identifier:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>36.6 | Initial Entry |

**7.a Unit:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**7.a Temperature Location:**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:50:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-14-2020<br>11:53:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-14-2020<br>11:53:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:53:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date                    | Location        | User                    | Value                            | Reason        |
|-------------------------|-----------------|-------------------------|----------------------------------|---------------|
| Aug-14-2020<br>11:53:03 | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| (UTC-03:00) City of Buenos Aires |  |  |  |  |
|----------------------------------|--|--|--|--|

5. Specimen Type:

| Date  | Location        | User                 | Value                       | Reason        |
|---|-----------------|----------------------|-----------------------------|---------------|
| Aug-14-2020 11:53:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

6.a

| Date  | Location        | User                 | Value  | Reason        |
|---|-----------------|----------------------|--|---------------|
| Aug-14-2020 11:53:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>Sponsor- 113<br>Defined Identifier:<br>Test:: Choriogon adotropin Beta_PX113<br>Result::<br>Not Done NOT DON<br>:: E | Initial Entry |

6.a Sponsor ID:

| Date  | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Aug-14-2020 11:53:03 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

**6.a Test:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Aug-14-2020<br>11:53:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Choriogonadotropin<br>Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Aug-14-2020<br>11:53:03<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Randomization Date :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Aug-14-2020<br>11:53:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-14-2020<br>11:53:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>228134 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-14-2020<br>14:13:32<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Aug-14-2020<br>14:13:32<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Aug-14-2020<br>14:14:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Aug-14-2020<br>14:13:32<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                  |   |                             |
|---|-----------------|------------------|---|-----------------------------|
|   |                 |                  |   | and correct as appropriate. |
| Aug-14-2020<br>14:13:32<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/14/2020 | Initial Entry               |

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

| Date  | Location        | User                      | Value             | Reason  |
|---|-----------------|---------------------------|-------------------|---|
| Aug-17-2020<br>16:28:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed   | Response satisfies query  |
| Aug-17-2020<br>09:00:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Answered | data updated  |
| Aug-17-2020<br>02:58:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | Katherine Liau<br>(b) (4) | Query 1: Opened   | Subject is listed to have:3 serum samples, which is less than the 5 expected. Please review and update Q4 as appropriate, else clarify. |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-14-2020<br>14:14:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BP5H0<br>: R | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-14-2020<br>14:14:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP5H0R | Initial Entry |

5.b

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-14-2020<br>14:14:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BP5H0<br>: S | Initial Entry |

5.b Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-14-2020<br>14:14:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP5H0S | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.c**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-14-2020<br>14:14:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BP5H0<br>: T | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-14-2020<br>14:14:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP5HOT | Initial Entry |

**5.d**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Aug-17-2020<br>09:00:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BLCSS<br>: 2 | Initial Entry |

**5.d Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-17-2020<br>09:00:22<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BLCSS2 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

*5.e*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-17-2020<br>09:00:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID</b> BLCSS<br>: 3 | Initial Entry |

*5.e Sample ID*

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Aug-17-2020<br>09:00:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BLCSS3 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Aug-14-2020<br>14:04:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Aug-14-2020<br>14:04:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Aug-14-2020<br>14:05:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Aug-14-2020<br>14:04:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                  |   |                             |
|---|-----------------|------------------|---|-----------------------------|
|   |                 |                  |   | and correct as appropriate. |
| Aug-14-2020<br>14:04:58<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Aug/14/2020 | Initial Entry               |

**5.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Aug-14-2020<br>14:05:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID</b> BP5H0<br>: 5 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Aug-14-2020<br>14:05:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BP5H05 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Aug/14/2020 10:46 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPE<br>CIFIED OBSERVATIO<br>N PERIOD | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Aug-14-2020<br>11:54:07<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Aug-14-2020<br>11:54:12<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES - REACTOGEN<br>ICITY E-DIARY CO<br>LLECTED FOR THI<br>S SUBJECT | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020<br>11:34:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Sep/4/2020 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>F<br>E<br>V<br>E<br>R<br><br>Were fever or sy N<br>stemic symptom O<br>s present on the<br>last day the Sub<br>ject Diary was c<br>ompleted?: | Initial Entry |

**2.a Symptom:**

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Sep-04-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

11:36:48  
(UTC-03:00) City  
of Buenos Aires

(b) (4),  
(b) (6)

FEVER

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.b

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> F<br>A<br>T<br>I<br>G<br>U<br>E<br><br><b>Were fever or s</b> N<br><b>ystemic sympto</b> O<br><b>ms present on t</b><br><b>he last day the S</b><br><b>ubject Diary wa</b><br><b>s completed?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.b Symptom:

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> HE<br>AD<br>AC<br>HE<br><b>Were fever or s</b> NO<br><b>ystemic sympto</b><br><b>ms present on t</b><br><b>he last day the</b><br><b>Subject Diary</b><br><b>was completed?</b><br>: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.c Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> C<br>HI<br>L<br>LS<br><b>Were fever or sy N</b><br><b>stemic symptom O</b><br><b>s present on the</b><br><b>last day the Sub</b><br><b>ject Diary was c</b><br><b>ompleted?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.d Symptom:

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MI<br>TI<br>NG<br><b>Were fever or s</b> NO<br><b>ystemic sympto</b><br><b>ms present on t</b><br><b>he last day the</b><br><b>Subject Diary</b><br><b>was completed</b><br><b>?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.e Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> DI<br>AR<br>RH<br>EA<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b><br>:<br>N<br>O | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

2.f Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW<br>OR W<br>ORSE<br>NED<br>MUS<br>CLE P<br>AIN | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | Were fever or NO<br>r systemic sy<br>mptoms pre<br>sent on the l<br>ast day the S<br>ubject Diary<br>was complet<br>ed?: |  |
|--|--|--|--|--|

2.g Symptom:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR WORSEN<br>ED MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.h

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW<br>OR W | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY -  
SYMPTOM RESOLVED DATES - eCRF Audit Trail  
History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411117**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

|                 |  |  |   |  |
|-----------------|--|--|---|--|
| of Buenos Aires |  |  | ORSE<br>NED<br>JOIN<br>T PAI<br>N<br><br>Were fever o<br>r systemic sy<br>mptoms pres<br>ent on the la<br>st day the Su<br>bject Diary<br>was complet<br>ed?: |  |
|-----------------|--|--|---|--|

**2.h Symptom:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR WORSEN<br>ED JOINT PAIN | Initial Entry |

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Injection Site Location:**

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**4. Injection Site Body Side:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**5.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RE<br>D<br>NE<br>SS<br><br><b>Were injection site reactions pre O sent on the last day the Subject Diary was completed?:</b> | Initial Entry |

**5.a Injection Site Reaction:**

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>REDNESS | Initial Entry |

*5.a Were injection site reactions present on the last day the Subject Diary was completed?*

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*5.b*

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site</b> SW<br><b>Reaction::</b> EL<br>LI<br>NG<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.b Injection Site Reaction:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> PAI<br>N AT<br>INJE<br>CTI<br>ON<br>SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |    |
|--|--|--|---|----|
|  |  |  | Were injections present on the last day the Subject Diary was completed?: | NO |
|--|--|--|---|----|

**5.c Injection Site Reaction:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-04-2020<br>11:36:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date:**

| Date  | Location        | User             | Value                            | Reason        |
|---|-----------------|------------------|----------------------------------|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sep/4/2020 | Initial Entry |

**2.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b><br><b>Temperature:</b> 36.7<br><b>Temperature Unit:</b><br><b>Temperature Location:</b> ORAL CAVIT<br><b>:</b> Y | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.a Temperature:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>36.7 | Initial Entry |

**2.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Sep-04-2020<br>11:37:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>ORAL CAVITY | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020<br>11:38:23<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-04-2020<br>11:38:23<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Sep-04-2020<br>11:38:23<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Sep/4/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date                    | Location        | User                    | Value                            | Reason        |
|-------------------------|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020<br>11:38:23 | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| (UTC-03:00) City of Buenos Aires |  |  |  |  |
|----------------------------------|--|--|--|--|

5. Specimen Type:

| Date   | Location        | User                 | Value                       | Reason        |
|--|-----------------|----------------------|-----------------------------|---------------|
| Sep-04-2020 11:38:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

6.a

| Date   | Location        | User                 | Value  | Reason        |
|--|-----------------|----------------------|--|---------------|
| Sep-04-2020 11:38:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-</b> 113<br><b>Defined Identifier:</b><br><b>Test::</b> Choriogon adotropin Beta_PX113<br><b>Result::</b><br><b>Not Done</b> NOT DON<br><b>::</b> E | Initial Entry |

6.a Sponsor ID:

| Date   | Location        | User                 | Value                     | Reason        |
|--|-----------------|----------------------|---------------------------|---------------|
| Sep-04-2020 11:38:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

**6.a Test:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Sep-04-2020<br>11:38:23<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Choriogonadotropin<br>Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-04-2020<br>11:38:23<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-04-2020<br>14:20:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-04-2020<br>14:20:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Sep-04-2020<br>14:20:52<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Sep-04-2020<br>14:20:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                  |  |                             |
|---|-----------------|------------------|--|-----------------------------|
|   |                 |                  |  | and correct as appropriate. |
| Sep-04-2020<br>14:20:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Sep/4/2020 | Initial Entry               |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Sep-04-2020<br>14:20:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample I</b> BPWXH<br><b>D:</b> T | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-04-2020<br>14:20:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BPWXHT | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                | Value                                  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Sep/4/2020 09:19 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

5. Anatomical Location:

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPE<br>CIFIED OBSERVATIO<br>N PERIOD | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***11. Was the subject observed for at least the protocol specified observation period after investigational product administration?***

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Sep-04-2020<br>11:39:11<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-02-2020<br>15:53:36<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Oct/2/2020 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptom::</b> F<br>E<br>V<br>E<br>R<br><br>Were fever or sy N<br>stemic symptom O<br>s present on the<br>last day the Sub<br>ject Diary was c<br>ompleted?: | Initial Entry |

**2.a Symptom:**

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Oct-02-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

|   |                     |       |
|---|---------------------|-------|
| 15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | (b) (4),<br>(b) (6) | FEVER |
|---|---------------------|-------|

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.b

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptom::</b> FA<br>TI<br>G<br>U<br>E<br><br><b>Were fever or s</b> N<br><b>ystemic sympto</b> O<br><b>ms present on t</b><br><b>he last day the S</b><br><b>ubject Diary wa</b><br><b>s completed?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

2.b Symptom:

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> HE<br>AD<br>AC<br>HE<br><b>Were fever or s</b> NO<br><b>ystemic sympto</b><br><b>ms present on t</b><br><b>he last day the</b><br><b>Subject Diary</b><br><b>was completed?</b><br>: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

2.c Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> C<br>HI<br>L<br>LS<br><b>Were fever or sy N</b><br><b>stemic symptom O</b><br><b>s present on the</b><br><b>last day the Sub</b><br><b>ject Diary was c</b><br><b>ompleted?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

2.d Symptom:

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.e

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MI<br>TI<br>NG<br><b>Were fever or s</b> NO<br><b>ystemic sympto</b><br><b>ms present on t</b><br><b>he last day the</b><br><b>Subject Diary</b><br><b>was completed</b><br><b>?:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

2.e Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.f

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> DI<br>AR<br>RH<br>EA<br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b><br>N<br>O<br>:<br>: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

2.f Symptom:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.g

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW<br>OR W<br>ORSE<br>NED<br>MUS<br>CLE P<br>AIN | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | Were fever or NO<br>r systemic sy<br>mptoms pre<br>sent on the l<br>ast day the S<br>ubject Diary<br>was complet<br>ed?: |  |
|--|--|--|--|--|

2.g Symptom:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR WORSEN<br>ED MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

2.h

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW<br>OR W | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1241**Site Name:** (1241) Hospital Irma Dulce**Subject No:** 12411117**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

|                 |  |  |  |  |
|-----------------|--|--|--|--|
| of Buenos Aires |  |  | ORSE<br>NED<br>JOIN<br>T PAI<br>N<br><br>Were fever or<br>r systemic sy<br>mptoms pres<br>ent on the la<br>st day the Su<br>bject Diary<br>was complet<br>ed?: |  |
|-----------------|--|--|--|--|

**2.h Symptom:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR WORSEN<br>ED JOINT PAIN | Initial Entry |

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Injection Site Location:**

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**4. Injection Site Body Side:**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**5.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Injection Site Reaction: RE<br>D<br>NE<br>SS<br><br>Were injection site reactions present on the last day the Subject Diary was completed?: | Initial Entry |

**5.a Injection Site Reaction:**

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>REDNESS | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.b

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site</b> SW<br><b>Reaction::</b> EL<br>LI<br>NG<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

5.b Injection Site Reaction:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> PAI<br>N AT<br>INJE<br>CTI<br>ON<br>SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

|  |  |  |   |    |
|--|--|--|---|----|
|  |  |  | Were injections present on the last day the Subject Diary was completed?: | NO |
|--|--|--|---|----|

5.c Injection Site Reaction:

| Date  | Location        | User             | Value                                 | Reason        |
|---|-----------------|------------------|---------------------------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date  | Location        | User             | Value             | Reason        |
|---|-----------------|------------------|-------------------|---------------|
| Oct-02-2020<br>15:54:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-06-2020<br>07:15:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-06-2020<br>07:15:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Oct-06-2020<br>07:15:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Oct-06-2020<br>07:15:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1241 Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                  |  |                             |
|---|-----------------|------------------|--|-----------------------------|
|   |                 |                  |  | and correct as appropriate. |
| Oct-06-2020<br>07:15:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/2/2020 | Initial Entry               |

5.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-06-2020<br>07:15:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BPVY6<br>: S | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-06-2020<br>07:15:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BPVY6S | Initial Entry |

5.b

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-06-2020<br>07:16:10<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample I BRXGC<br>D: R | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-06-2020<br>07:16:10<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BRXGCR | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-06-2020<br>07:16:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample I</b> BRXGC<br><b>D:</b> S | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-06-2020<br>07:16:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BRXGCS | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User             | Value                     | Reason   |
|--|-----------------|------------------|---------------------------|--|
| Jan-22-2021<br>10:27:45<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed           | Response satisfies query   |
| Jan-21-2021<br>09:56:04<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered         | data updated   |
| Jan-21-2021<br>04:27:58<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued: Opened | 'Microbiology Specimen form' is a required form. If not done, then form should be marked Not Done at the form level. Please remove all entered data using the eraser icon, then the option to tick Not Done/Not Applicable at the form level |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                        |                          |  |
|--|-----------------|------------------------|--------------------------|--|
|  |                 |                        |                          | will be available.   |
| Jan-20-2021<br>10:02:48<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Answered        | data updated. Subject refused the test at the local lab                            |
| Jan-18-2021<br>05:12:26<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Reissued:Opened | DM : Please review and update COVID TEST form if data is available now. Thank you. |
| Jan-15-2021<br>10:56:52<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Answered        | Result not available   |
| Dec-31-2020<br>01:19:27<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 3: Opened          | DM: Kindly consider to update missing COVID TEST form or else clarify. Thank you.  |
| Dec-28-2020<br>11:38:29<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted         | Close Auto Query   |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                           |                                   |  |
|--|-----------------|---------------------------|-----------------------------------|--|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                  | Close Auto Query   |
| Dec-28-2020<br>11:26:35<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Candidate                | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.          |
| Dec-28-2020<br>11:26:35<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate                | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Dec-28-2020<br>11:26:35<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Dec/28/2020 | Initial Entry  |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**3. COVID-19 Illness Visit:**

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Dec-28-2020<br>11:26:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_A | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Assessment:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Dec/28/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Dec/24/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date   | Location        | User                | Value   | Reason             |
|--|-----------------|---------------------|---|--------------------|
| Jan-25-2021<br>09:59:50<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO<br>Date of Last Sympt<br>om Resolved:<br><br>Dec/29/2020 | New<br>Information |
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES   | Initial Entry      |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEV<br>ER<br><b>Symptom Pr</b> NO<br><b>esent:</b> | Initial Entry |

**4.a Symptoms:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**4.a Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.b**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sympt</b> NEW OR I<br><b>oms:</b> NCREASE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|                 |  |  |                             |  |
|-----------------|--|--|-----------------------------|--|
| of Buenos Aires |  |  | D COUGH                     |  |
|                 |  |  | <b>Symptom Present:</b> YES |  |

**4.b Symptoms:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED COUGH | Initial Entry |

**4.b Was symptom present?**

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**4.c**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Symp NO<br/>tom<br/>Prese<br/>nt:</b> |  |
|--|--|--|--|--|

**4.c Symptoms:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR INCREAS<br>ED SHORTNESS OF<br>BREATH | Initial Entry |

**4.c Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.d**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptoms:</b> CHIL<br>LS<br><b>Symptom Pr</b> NO<br><b>esent:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.d Symptoms:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

**4.d Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.e**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Sympt NEW OR IN<br>oms: CREASED<br>MUSCLE P<br>AIN<br>Sympt YES<br>om Pr<br>esent: | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.e Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR INCREAS<br>ED MUSCLE PAIN | Initial Entry |

**4.e Was symptom present?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

**4.f**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sympt</b> NEW LOSS<br><b>oms:</b> OF TASTE<br>OR SMELL<br><b>Sympt</b> NO<br><b>om Pr</b><br><b>esent:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.f Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW LOSS OF TAS<br>TE OR SMELL | Initial Entry |

**4.f Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.g**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sympt NEW OR IN</b><br><b>oms: CREASED S</b><br><b>ORE THRO</b><br><b>AT</b><br><b>Sympt YES</b><br><b>om Pr</b><br><b>esent:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.g Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NEW OR INCREAS<br>ED SORE THROAT | Initial Entry |

**4.g Was symptom present?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

**4.h**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARR<br>HEA<br><b>Symptom NO</b><br><b>Present:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.h Symptoms:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**4.h Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.i**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMIT<br>ING<br><b>Symptom</b> NO<br><b>Present:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL  
COVID-19 - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**4.i Symptoms:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:27:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Actual Date of Collection:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:53:59<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:54:12<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|--|-----------------|---------------------|--------------------------------|---------------|

**3. Specimen Collection Location:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:54:25<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:55:36<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City                    | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
| of Buenos Aires  |                 |                     |                                |               |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:55:36<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**6. Trade Name:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:54:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021  | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b>             | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
| 09:53:39<br>(UTC-03:00) City<br>of Buenos Aires                |                 | (b) (4),<br>(b) (6) |                                |               |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**7. Test Result:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:54:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**8. Comments/Findings/Details:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:55:05<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**9. Trade Name Other, Specify:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-21-2021<br>09:55:17<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
| Jan-21-2021<br>09:53:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b>             | Initial Entry |
| Jan-15-2021<br>12:30:02<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-28-2020<br>11:28:08<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-28-2020<br>11:28:08<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:08<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Dec-28-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |  |                     |                            |  |
|---|--|---------------------|----------------------------|--|
| 11:28:08<br>(UTC-03:00) City<br>of Buenos Aires |  | (b) (4),<br>(b) (6) | Subject used site swa<br>b |  |
|---|--|---------------------|----------------------------|--|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-28-2020<br>11:38:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Dec-28-2020<br>11:38:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Dec-28-2020<br>11:38:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Dec-28-2020<br>11:38:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |   |                             |
|--|-----------------|---------------------|---|-----------------------------|
|  |                 |                     |   | and correct as appropriate. |
| Dec-28-2020<br>11:38:29<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/28/2020 | Initial Entry               |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:38:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR7963 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-28-2020<br>11:38:39<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BR7963 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

***1.a***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Type of Prac</b> SPEC<br><b>titioner:</b> IALI<br>ST<br><b>Occurrence o</b> NO<br><b>f Visits or Co</b><br><b>ntacts:</b> | Initial Entry |

***1.a Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

***1.a Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.b***

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Type of Pr</b> EMER<br><b>actioner:</b> GENCY<br>ROOM<br><b>Occurrence</b> NO<br><b>of Visits</b><br><b>or Contact</b><br><b>s:</b> | Initial Entry |

*1.b Physician or Healthcare Professional:*

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>EMERGENCY ROO<br>M | Initial Entry |

*1.b Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.c*

| Date                    | Location        | User                | Value   | Reason        |
|-------------------------|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:28:28 | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Type of P</b> PRIMAR | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|                                  |  |                  |   |
|----------------------------------|--|------------------|---|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | <b>ractitioner:</b> Y CARE PHYSICIAN<br><b>Occurrence of Visits or Contacts:</b> NO |
|----------------------------------|--|------------------|---|

***1.c Physician or Healthcare Professional:***

| Date  | Location        | User             | Value                                     | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-28-2020 11:28:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> PRIMARY CARE PHYSICIAN | Initial Entry |

***1.c Occurrence of Visits or Contacts:***

| Date  | Location        | User             | Value                 | Reason        |
|---|-----------------|------------------|-----------------------|---------------|
| Dec-28-2020 11:28:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> NO | Initial Entry |

***1.d***

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-28-2020 11:28:28 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> Type of Practitioner: URGENT CARE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Occurrence NO<br/>of Visits or<br/>Contacts:</b> |  |
|--|--|--|---|--|

***1.d Physician or Healthcare Professional:***

| <b>Date</b>  | <b>Location</b> | <b>User</b>         | <b>Value</b>                      | <b>Reason</b> |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

***1.d Occurrence of Visits or Contacts:***

| <b>Date</b>  | <b>Location</b> | <b>User</b>         | <b>Value</b>             | <b>Reason</b> |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.e***

| <b>Date</b>  | <b>Location</b> | <b>User</b>         | <b>Value</b>  | <b>Reason</b> |
|--|-----------------|---------------------|---|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Type of P</b> TELEPH<br><b>ractitione</b> ONE CO<br><b>r:</b> NSULTA<br>TION<br><b>Occurren</b> NO<br><b>ce of Visit</b><br><b>s or Cont</b><br><b>acts:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.e Physician or Healthcare Professional:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>TELEPHONE CONS<br>ULTATION | Initial Entry |

***1.e Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.f***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Type of Practit</b> OT<br><b>ioner:</b> HE<br>R<br><b>Occurrence of</b> NO<br><b>Visits or Conta</b><br><b>cts:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

***1.f Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

***1.f Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/28/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-28-2020<br>11:28:40<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-<br>19 ILLNESS | Initial Entry |

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-28-2020<br>11:28:40<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Toxicity Grade:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-28-2020<br>11:28:40<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Visit**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-25-2021<br>10:00:08<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/25/2021 | Initial Entry |

**3. COVID-19 Illness Visit:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-25-2021<br>10:00:08<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COVID_A1 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-25-2021<br>12:03:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-25-2021<br>12:03:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Jan-25-2021<br>12:03:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Jan-25-2021<br>12:03:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |   |                             |
|--|-----------------|---------------------|---|-----------------------------|
|  |                 |                     |   | and correct as appropriate. |
| Jan-25-2021<br>12:03:42<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/25/2021 | Initial Entry               |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-25-2021<br>12:03:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID</b> BPTKX<br>:<br>2 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-25-2021<br>12:03:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BPTKX2 | Initial Entry |

**5.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-25-2021<br>12:04:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample I</b> BSCYX<br><b>D:</b> Y | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/25/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-25-2021<br>12:04:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSCYXY | Initial Entry |

**5.c**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-25-2021<br>12:04:13<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID BSCYX</b><br>: Z | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-25-2021<br>12:04:13<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSCYXZ | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-02-2020<br>15:54:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Oct/2/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-02-2020<br>15:54:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Oct-02-2020<br>15:54:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Form Created |        |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Form Created |        |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Myalgia | Initial Entry |

**4. Start Date Time:**

| Date                    | Location        | User             | Value                                   | Reason        |
|-------------------------|-----------------|------------------|---|---------------|
| Feb-19-2021<br>10:58:19 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/30/2021 UNK:U | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |  |                  |    |  |
|----------------------------------|--|------------------|----|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | NK |  |
|----------------------------------|--|------------------|----|--|

5. Is the adverse event still ongoing?

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Feb-19-2021 10:58:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Feb/2/2021 UNK:<br>UNK | Initial Entry |

6. Toxicity Grade:

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Feb-19-2021 10:58:19 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Feb-19-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |  |                     |    |  |
|--|--|---------------------|----|--|
| 10:58:19<br>(UTC-03:00) City of Buenos Aires |  | (b) (4),<br>(b) (6) | NO |  |
|--|--|---------------------|----|--|

**8. Is this adverse event the result of a study Medication Error?  
If Yes, record the type of medication error on the Medication Error Log.**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date  | Location        | User             | Value                         | Reason        |
|---|-----------------|------------------|-------------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                           |               |
|--|-----------------|---------------------|---------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |
|--|-----------------|---------------------|---------------------------|---------------|

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>RECOVERED/RESO<br>LVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:58:19<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Category:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date  | Location        | User             | Value                                     | Reason        |
|---|-----------------|------------------|---|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Injection site pain | Initial Entry |

**4. Start Date Time:**

| Date        | Location        | User             | Value              | Reason        |
|-------------|-----------------|------------------|--------------------|---------------|
| Feb-19-2021 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|  |  |                     |                         |  |
|--|--|---------------------|-------------------------|--|
| 10:59:28<br>(UTC-03:00) City of Buenos Aires |  | (b) (4),<br>(b) (6) | Jan/30/2021 UNK:U<br>NK |  |
|--|--|---------------------|-------------------------|--|

5. Is the adverse event still ongoing?

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Feb/2/2021 UNK:<br>UNK | Initial Entry |

6. Toxicity Grade:

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|  |                 |                     |                          |               |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>RECOVERED/RESO<br>LVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:59:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241      **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-29-2021<br>12:02:50<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1241 **Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-29-2021<br>12:03:13<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Participant is willing to<br>return for Vaccination 3<br>Participant is:<br><br>eligible per local/n<br>ational recommen<br>dations and confir<br>med to have receiv<br>ed only placebo at<br>Vaccination 1/2 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date Treatment Unblinded :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-29-2021<br>12:02:34<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-29-2021<br>12:02:34<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>ASSESS ELIGIBILI<br>TY FOR ADDITION<br>AL VACCINATION | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-29-2021<br>12:03:24<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/29/2021 | Initial Entry |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER  
VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Consent Was:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-29-2021<br>12:03:31<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent<br>Obtained<br><br>Jan/29/2021 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-29-2021<br>12:04:01<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/29/2021 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                                       | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Jan-29-2021<br>12:04:01<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>REPEAT SCREENING<br>1 | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Jan-29-2021<br>12:04:01<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/29/2021 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date                    | Location        | User                    | Value                            | Reason        |
|-------------------------|-----------------|-------------------------|----------------------------------|---------------|
| Jan-29-2021<br>12:04:21 | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|                                  |  |  |  |  |
|----------------------------------|--|--|--|--|
| (UTC-03:00) City of Buenos Aires |  |  |  |  |
|----------------------------------|--|--|--|--|

5. Specimen Type:

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

6.a

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-</b> 113<br><b>Defined Identifier:</b><br><b>Test::</b> Choriogon<br>adotropin<br>Beta_PX11<br>3<br><b>Result::</b><br><b>Not Done</b> NOT DON<br><b>::</b> E | Initial Entry |

6.a Sponsor ID:

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

**6.a Test:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Choriogonadotropin<br>Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-29-2021<br>12:04:21<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-29-2021<br>14:24:33<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-29-2021<br>14:24:33<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Jan-29-2021<br>14:24:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Jan-29-2021<br>14:24:33<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                  |   |                             |
|---|-----------------|------------------|---|-----------------------------|
|   |                 |                  |   | and correct as appropriate. |
| Jan-29-2021<br>14:24:33<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/29/2021 | Initial Entry               |

5.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-29-2021<br>14:24:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample I</b> BR6GW<br><b>D:</b> L | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-29-2021<br>14:24:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BR6GWL | Initial Entry |

5.b

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-29-2021<br>14:24:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID</b> BSD7F<br>:<br>0 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-29-2021<br>14:24:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BSD7F0 | Initial Entry |

**5.c**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Jan-29-2021<br>14:24:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID</b> BSD7F<br>: 1 | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-29-2021<br>14:24:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BSD7F1 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-29-2021<br>14:03:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-29-2021<br>14:03:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Jan-29-2021<br>14:03:56<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Jan-29-2021<br>14:03:48<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

|   |                 |                  |   |                             |
|---|-----------------|------------------|---|-----------------------------|
|   |                 |                  |   | and correct as appropriate. |
| Jan-29-2021<br>14:03:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/29/2021 | Initial Entry               |

5.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-29-2021<br>14:03:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample I</b> BR6GW<br><b>D:</b> 2 | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-29-2021<br>14:03:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BR6GW2 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                          | Reason        |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/29/2021 09:47 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

of Buenos Aires

5. Anatomical Location:

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**9. Unit:**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30 MINUTES | Initial Entry |

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-29-2021<br>12:04:45<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Feb-19-2021<br>10:56:16<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Feb/19/2021 | Initial Entry |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Feb/19/2021 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date                    | Location        | User                    | Value                            | Reason        |
|-------------------------|-----------------|-------------------------|----------------------------------|---------------|
| Feb-19-2021<br>10:56:37 | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1241

Site Name: (1241) Hospital Irma Dulce

Subject No: 12411117

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

(UTC-03:00) City of Buenos Aires

5. Specimen Type:

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

6.a

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor- 113<br>Defined Identifier:<br>Test:: Choriogon<br>adotropin<br>Beta_PX11<br>3<br><b>Result::</b><br>Not Done NOT DON<br>:: E | Initial Entry |

6.a Sponsor ID:

| Date  | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST -  
eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:21

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

**6.a Test:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Choriogonadotropin<br>Beta_PX113 | Initial Entry |

**6.a Not Done:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Feb-19-2021<br>10:56:37<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-19-2021<br>10:10:30<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-19-2021<br>10:10:30<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value              | Reason  |
|--|-----------------|---------------------------|--------------------|---|
| Feb-19-2021<br>10:10:41<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query   |
| Feb-19-2021<br>10:10:30<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however<br>no barcodes<br>are entered.<br>Please review |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |                 |                  |   |                             |
|---|-----------------|------------------|---|-----------------------------|
|   |                 |                  |   | and correct as appropriate. |
| Feb-19-2021<br>10:10:30<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/19/2021 | Initial Entry               |

**5.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Feb-19-2021<br>10:10:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID</b> BRKFF<br>: 0 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Feb-19-2021<br>10:10:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BRKFF0 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                          | Reason        |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Feb/19/2021 09:50 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

of Buenos Aires

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

**8. Actual Dose:**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**9. Unit:**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30 MINUTES | Initial Entry |

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Feb-19-2021<br>10:56:58<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**1. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-02-2020<br>15:54:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Aug-14-2020<br>11:53:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Aug-14-2020<br>11:47:06<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-02-2020<br>15:54:35<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/2/2020  | Initial Entry |
| Aug-14-2020<br>11:53:38<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Aug/14/2020 | Initial Entry |
| Aug-14-2020  | ACV0PFEINFP6000 | auto calc               | <b>Data Entry:</b>                | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1241

**Site Name:** (1241) Hospital Irma Dulce

**Subject No:** 12411117

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

|   |  |            |             |  |
|---|--|------------|-------------|--|
| 11:47:06<br>(UTC-03:00) City<br>of Buenos Aires |  | (autocalc) | Aug/14/2020 |  |
|---|--|------------|-------------|--|

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1241

**Subject No:** 12411117

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1241) Hospital Irma Dulce

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

*1. Casebook Signature*

| Date   | Location        | User                        | Value                                      | Reason        |
|--|-----------------|-----------------------------|--|---------------|
| Sep-16-2020<br>18:53:28<br>(UTC-03:00) City<br>of Buenos Aires | ACV0PFEINFP6000 | Edson<br>Moreira<br>(b) (4) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |

090177e196ae3f79\Final\Final On: 01-Apr-2021 05:17 (GMT)